Remarks:

This Amendment is being filed responsive to the July 18, 2006 Office action that was issued in connection with the above-identified patent application. Prior to entry of this Amendment, claims 1-7 25-29 were pending in the application. The Examiner has provisionally rejected claims 1, 3-7, and 26-29 under the non-statutory, obvious-type double patenting doctrine over claim 1 of copending Application No. 10/801,380. In addition, claims 1, 3, 4, 6, 26, and 29 are provisionally rejected under the non-statutory, obvious-type double patenting doctrine over claims 1, 3, 4-6, and 29 of copending Application No. 10/801,381. The Examiner has rejected claim 25 under 35 U.S.C. 112 ¶ 2 as being indefinite. Claims 1-7 25-29 stand rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. 103(a), based on U.S. Patent No. 4,322,449 to Voss et al. ("Voss et al."). Claim 3 stands rejected under 35 U.S.C. § 103(a) based on Voss et al. in view of U.S. Patent No. 5,894,841 to Vogues ("Vogues"). Applicants respectfully traverse the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a).

Double Patenting Rejections

As suggested by the Examiner, Applicants have filed terminal disclaimers to address each provisional non-statutory double patenting rejection rendered for this Application. Accordingly, Applicants submit that claims 1, 3-7, and 26-29 provisionally rejected over claim 1 of copending Application No. 10/801,380 and claims 1, 3, 4, 6, 26, and 29 provisionally rejected over claims 1, 3, 4-6, and 29 of copending Application No. 10/801,381 are now in condition for allowance.

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Rejections under 35 U.S.C. 112 ¶ 2

In the interest of furthering prosecution of this application to issuance of a patent, applicants have amended claim 25 for clarity. Claim 25 recites:

> The method of claim 1, wherein selecting the desired dot topography includes selecting a textured topography to increase the dissolution rate of the bioactive agent or selecting a smooth topography to decrease the dissolution rate of the bioactive agent.

The terms "relatively irregular," "relatively faster," and "relatively slower," which the Examiner asserted were relative terms, have been replaced for clarity. In addition, the claim has been amended to clarify that it does not call for both a faster and a slower dissolution rate at the same time. Applicants submit that claim 25 as amended is definite under 35 U.S.C. § 112 ¶2.

Rejections under 35 U.S.C. 102(b) or in the alternative under 35 U.S.C. 103(a)

Claims 1-7 and 25-29 stand rejected under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. 103(a), based on to Voss et al. Voss et al. discloses a method for using a piezoelectric dosing system to dot a liquid active substance onto a substrate. The piezoelectric dosing system is shown below:

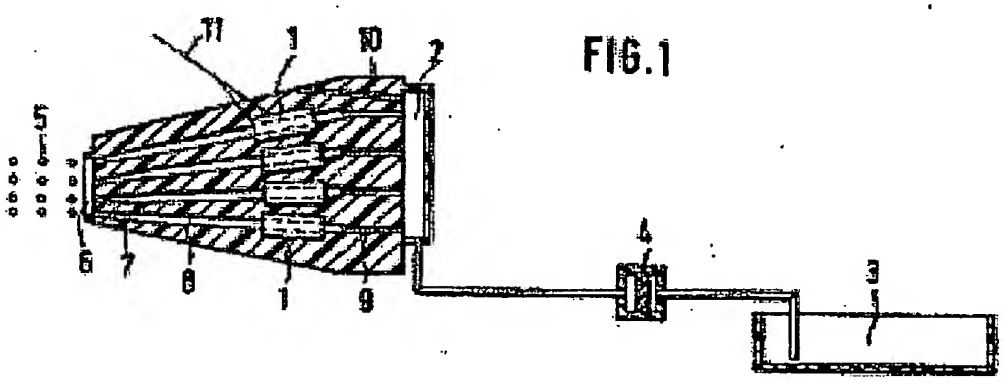

FIG.1

Voss et al. discusses controlling dosing at column 4, lines 13-26 as follows:

> The dosing may be controlled by one or more of the following parameters:
> (a) the diameter of the outlet opening of the nozzle channels;
> (b) the voltage applied to the piezoelectric oscillator;
> (c) the droplet frequency;
> (d) the number of nozzle channels;
> (e) the stroke intensity of the tubular or planar oscillator used;
> (f) the active substance concentration of the solution or suspension; and
> (g) the number of dots of active substance per pharmaceutical carrier.

While Voss et al. al. discloses a number of means for controlling dosing, it does not address each feature recited in the claims.

Claims 1, 2, 4-7, and 25

Voss et al. does not disclose or suggest each feature recited in independent claim 1. Claim 1 recites:

> A method of controlling a dissolution rate of a bioactive agent, the method comprising:
> identifying a target dissolution rate;
> selecting a desired dot topography corresponding to the target dissolution rate; and
> applying a bioactive agent to a delivery substrate to form dots having the desired dot topography on the delivery substrate.

Voss et al. does not disclose or suggest a method comprising selecting a desired dot topography corresponding to a target dissolution rate as recited in claim 1. While Voss et al. lists certain parameters to control dosing, it does not disclose dot topography as a characteristic used for control purposes and it does not disclose controlling

dissolution rate. Instead, dot topography is not addressed, and Voss et al. pertains to controlling dosing as distinct from controlling dissolution rate.

1. *Dissolution rate.*

The Examiner acknowledges that Voss et al. does not disclose or suggest identifying a target dissolution rate. However, she takes the position that it would have been inherent to identify a target dissolution rate when selecting a target dose. Applicants respectfully disagree with this position. The Examiner equates a *target* dissolution rate with an *acceptable* dissolution rate, i.e. a rate that is not too rapid and not too slow. However, a target dissolution rate is more specific than an acceptable dissolution rate. There is typically a range of dissolution rates that provide acceptable dosing, but one may desire to target one specific dissolution rate to achieve a variety of objectives. Claim 1 recites selecting a target dissolution rate, not selecting a target dose and ensuring that its dissolution rate is acceptable.

Moreover, Voss et al. does not disclose or suggest means for achieving a target dissolution rate. Claim 1 recites selecting a desired dot topography corresponding to the target dissolution rate and applying a bioactive agent to a delivery substrate to form dots having the desired dot topography. Voss et al. discloses means for achieving a target dose, such as in Example 2 where the concentration of each drop was adjusted so that 250 drops would provide 0.1 mg of active substance. Means to achieve a desired dose, or quantity of active substance, on a substrate is not the same as means to achieve a desired dissolution rate. Thus, Voss et al. does not disclose or suggest means to achieve a target dissolution rate.

2. *Dot topography*

Voss et al. does not disclose or suggest selecting a desired dot topography. In fact, to the best of Applicants' knowledge, Voss et al. does not mention dot topography. While Voss et al. discusses dot size and to some extent dot shape, those characteristics are distinct from dot topography. Distinguishing dot shape from dot topography, the specification recites that "dot shape refers to the general shape of a dot without reference to surface detail, and dot topography is used to refer to surface detail of the dot." (p. 18, ln. 20-22). Thus, without mention of dot topography, Voss et al. does not disclose or suggest selecting a desired dot topography.

Further, Voss et al. does not disclose or suggest correlating dot topography with a target parameter, such as a dissolution rate of a bioactive agent. Claim 1 recites selecting a desired dot topography corresponding to a target dissolution rate. Voss et al. does not mention dot topography and it further doesn't disclose or suggest using dot topography to control a target parameter, such as dissolution rate. Creating a desired effect through selection of a particular dot topography is simply not addressed or suggested by Voss et al.

Voss et al. does not disclose or suggest applying a bioactive agent to a delivery substrate to form dots having the desired dot topography. While Voss et al. discloses applying patterns of dots to form letters or labeling, it does not disclose or suggest applying dots in a manner to achieve different dot topographies. Instead, Voss et al. discloses applying uniform dots of a specific concentration so that "extremely accurate dosing is made possible." (Col. 5, ln. 64).

For at least the reasons discussed above, Voss et al. does not disclose or suggest each feature recited in claim 1. Accordingly, Voss et al. does not anticipate claim 1 under 35 U.S.C. § 102(b) or make a *prima facie* case that it is obvious under 35 U.S.C. § 103(a). It follows then that such rejections can not stand for claims 2, 4-7, and 25 depending from claim 1. Applicants, therefore, submit that the aforementioned claims are allowable.

Claims 26 and 28

Voss et al. does not disclose or suggest each feature recited in independent claim 26. Claim 26 recites:

> A method of controlling dissolution rate of a bioactive agent, the method comprising:
> identifying a target dissolution rate;
> selecting a dot topography based on the target dissolution rate; and
> applying a bioactive agent to a delivery substrate to form dots having the selected dot topography, thereby achieving the identified target dissolution rate.

1. *Dissolution rate.*

Identifying a target dissolution rate is not disclosed or suggested in Voss et al. The Examiner acknowledges this omission, but she takes the position that it would be inherent to one skilled in the art to identify a target dissolution rate. Applicants respectfully disagree with this position because a target dissolution rate is more than just an acceptable dissolution rate that a particular dose happens to provide. Identifying a target dissolution rate provides certain specificity and control over the release profiles of a bioactive agent that are not present when only the dose, or quantity, of a substance is selected as in Voss et al.

Moreover, Voss et al. does not disclose or suggest achieving the identified target dissolution rate. The only mention of dissolution rate made in Voss et al. is in the background section stating that traditional tablet pressing techniques can negatively influence dissolution rate. It does not disclose or suggest methods or steps to achieve an identified dissolution rate. Instead, Voss et al. provides a method for achieving a particular dose. A dose of a bioactive agent can be administered in a range of dissolution rates, claim 26 provides a method for controlling which dissolution rate the agent will have.

2. *Dot topography.*

Voss et al. does not disclose or suggest selecting a dot topography. Dot topography is not addressed in Voss et al., but instead it addresses parameters like the concentration of active substance in a drop and the size and weight of a drop. Dot topography is a characteristic unique from the size, weight, and concentration of a drop; thus, the reference does not disclose or suggest selecting a dot topography as recited in claim 26.

Further, selecting a dot topography based on a target dissolution rate is not disclosed or suggested by Voss et al. The reference's failure to mention dot topography or a target dissolution rate precludes it from disclosing a method including selecting a dot topography based on a target dissolution rate.

Voss et al. does not disclose applying a bioactive agent to form dots having a selected dot topography. While Applicants disclosure provides means for applying dots having a selected dot topography, such as recited in claim 26, Voss et al. does not

mention dot topography or means to form dots with a selected topography. Rather, Voss et al. describes applying dots of uniform size, weight, and concentration.

For the reasons discussed, Voss et al. does not disclose each feature recited in claim 26. Thus, claim 26 is not anticipated under 35 U.S.C. § 102(b) by Voss et al. and the reference does not establish a *prima facie* case that claim 26 is obvious under 35 U.S.C. § 103(a). It follows then that claim 28 depending from claim 26 is not anticipated or obvious. Therefore, Applicants request allowance of claims 26 and 28.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claim 3 as being unpatentable over Voss et al. in view of Voges. However, Applicants submit that the proposed combination does not disclose or suggest each feature recited in claim 3. Claim 3 recites:

> The method of claim 1, wherein applying the bioactive agent to the delivery substrate includes heating a solution carrying the bioactive agent with a thermal ejection element.

Combining Voss et al. with Voges does not disclose or suggest each feature of claim 3. The Examiner notes that Voss et al. does not disclose thermal ejection elements and cites Voges for such disclosure. However, any disclosure in Voges directed to thermal ejection elements is rendered irrelevant by the fact that numerous other features of claim 3 are not disclosed by the proposed combination. For example, the combination does not disclose identifying a target dissolution rate, selecting a desired dot topography corresponding to the target dissolution rate, or applying a bioactive agent to a delivery substrate to form dots having the desired dot topography. Accordingly, the proposed combination does not establish a *prima facie* case that claim 3 is obvious under 35 U.S.C. § 103(a).

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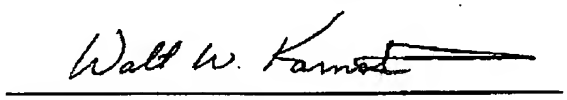
Conclusion

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

KOLISCH HARTWELL, P.C.



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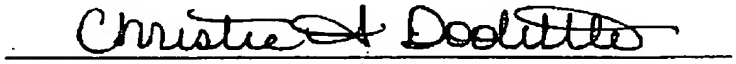
CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner J. Michener, Group Art Unit 1762, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on October 5, 2006.



Christie A. Doolittle